

## **REMARKS**

Claims 1-7, 9-17, 19-28, 30-38, 40-49, 51-59 and 61-65 remain pending in this application.

### **Response To Pending Rejections**

The applicant thanks the Examiner for favorably considering the arguments and amendment with respect to the prior art formerly cited.

#### ***Response to Arguments***

**Item 5.** The Examiner states that the “[a]pplicant's arguments filed have been fully considered but they are not persuasive.” The Examiner’s statement is reproduced in full below.

Regarding the rejection of claims 1,2,4, 7, 9-16, 19-24,28, 30-37 and 40-44 under 35 U.S.C. 102(b) as anticipated by Younghusband et al., Applicants argue that the term "sequential" with respect to method steps does not imply that there are intervening steps between two sequential steps, and Younghusband et al. teach such intervening steps. However, the preamble to claim 1 (and 2) contains the following phrase: "comprising the following sequential steps". As noted in MPEP 2111.3: 2111.03 **Transitional Phrases [R-3]** The transitional phrases "comprising", "consisting essentially of and "consisting of define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim.

The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., >Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369,1376,71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term 'comprising,' the terms 'containing' and 'mixture' are open-ended.")^ Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368,66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608,1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research

Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448,450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). >In Gillette Co. v. Energizer Holdings Inc., 405 F.3d 1367,1371-73, 74 USPQ2d 1586,1589-91 (Fed. Cir. 2005), the court held that a claim to "a safety razor blade unit comprising a guard, a cap, and a group of first, second, and third blades" encompasses razors with more than three blades because the transitional phrase "comprising" in the preamble and the phrase "group of are presumptively open-ended. "The word 'comprising' transitioning from the preamble to the body signals that the entire claim is presumptively open-ended." Id. In contrast, the court noted the phrase "group consisting of is a closed term, which is often used in claim drafting to signal a "Markush group" that is by its nature closed. Id. The court also emphasized that reference to "first," "second," and "third" blades in the claim was not used to show a serial or numerical limitation but instead was used to distinguish or identify the various members of the group. Id." Therefore, the presence of the phrase "comprising" implies that additional steps between the sequential steps are permitted, and thus Younghusband et al. anticipate the claims.

It is once again respectfully pointed out to the Examiner that although the claim includes the transitional term "comprising, this term is subjected to the limitations of the term "sequential steps." As pointed out to the Examiner in the Response dated September 19, 2006, the term sequential in respected dictionaries is defined as: "following; subsequent; consequent." The term sequential does not imply that there are intervening steps in between two sequential steps; it means that the steps as recited are followed one after another. As stated in the specification on page 7, lines 19-20, "[t]he invention of the current method allows the cells to be directly suspended in a hypertonic, high-salt reagent, followed by the addition of a lysis reagent." Moreover, as described on page 20, lines 12-14 , "[i]mmediately following this step [suspension of cells in the hypotonic, high-salt solution], a volume of 10 ml cell lysis solution . . . was added to the sample to lyse the cells." Moreover, the method of the invention teaches that the cell lysis solution is sequentially added to the suspension of cells.

Thus, to the extent that the transitional phrase "comprising" applies in this instance, it may encompass steps only following the "sequential steps" (a) through (d) as taught by the invention. Indeed, for the method to work as taught by the invention, each of the steps (a)

through (d) must follow each other. This aspect of the invention is not taught in Younghusband.

Indeed, the Gillette reference cited by the Examiner to make her point that the term comprising implies that additional steps between the sequential steps are permitted, in fact distinguishes the invention in Gillette in which various members of a group are identified (a group of first, second and third blades, in claim 1 of the '777 patent identified in Gillette), and inventions such as one taught in the present case in which elements must necessarily appear in a prescribed order (sequential steps). Gillette clearly distinguishes the former from the latter as follows:

None of the blades in the "group" are defined by their consecutive order relative to the other blades.

To make it abundantly clear that the reference to "first," "second," and "third" blades was not a serial or numerical limitation, the claim does not follow a consecutive order (i.e., it does not discuss the second blade after the first). The claim is thus clearly not using the ordinals-first, second, third-to show a consecutive numerical limit but only to distinguish or identify the various members of the group.

See Gillette at 17 (emphasis added).

In contrast, the elements of the claims of the present invention are clearly written to show that step (d) follows step (c), which follows step (b), which in turn follows step (a), *i.e.*, the steps of the claim follow a sequential (or consecutive) order. Unlike claim 1 discussed in Gillette, the claim of the present invention itself makes this distinction, and imposes a serial limitation on the claim. Moreover, unlike the open-ended term "a group of" in claim 1 of the '777 patent which in patent-law convention is intended to allow for additional elements, the term "sequential steps" in the claims of the present invention show that each step is defined by its consecutive order relative to the other steps. The Examiner, however, overlooks this very important distinction, a distinction that was deemed important enough to be specifically addressed by the Federal Circuit in Gillette. In overlooking this fundamental distinction made in Gillette, the Examiner incorrectly interjects the claims of the present invention with a meaning that the ruling in Gillette specifically intended to avoid.

Thus, the Examiner is requested to re-consider the arguments raised in the response dated September 19, 2006 in light of the teachings of Gillette. By doing so, the Examiner will undoubtedly distinguish the method of the present invention over Younghusband, and be persuaded that Younghusband does not meet the limitations of the instant claims.

***Claim Rejections - 35 USC §102***

Item 6. The Examiner states that “[c]laims 1-2,4, 7, 9-16, 19-24, 28, 30-37, 40-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Younghusband et al. (J virology, Vo. 43, No. 2, pp. 705-713,1982).”

The Examiner is respectfully directed to the arguments in Item 5. that negate this anticipation rejection.

***Claim Rejections - 35 USC §103***

Item 8. In addressing the issue of joint inventors for the instant application, the Examiner states that “[i]n considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

The Examiner is correct in presuming that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made.

Item 8. The Examiner states that “[c]laims 3-6, 17, 25-27, 38, 45-49, 51-59, 61-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Younghusband et al. . . . in view of Gray et al. . . .”

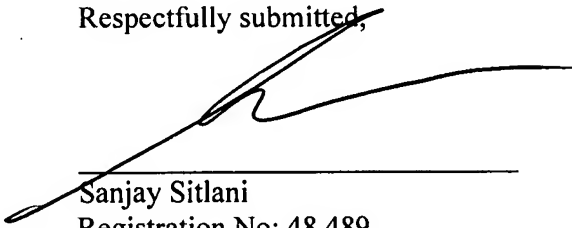
As pointed out to the Examiner in the aforementioned arguments with respect to Younghusband, Younghusband does not meet the limitations of the instant claims and that the method of the claimed invention is distinct and unique over Younghusband. The combined references of Younghusband and Gray do not render the instant invention obvious. None of the teachings in Gray would suggest to one of ordinary skill in the art to invent a method comprising the specific sequential steps as taught in the instant invention.

Based on the remarks above, applicant believes all pending claims are in condition for allowance.

If the Examiner believes that a conference would be of value in expediting the prosecution of this application, the Examiner is hereby invited to telephone undersigned counsel to arrange for such a conference.

Respectfully submitted,

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Date

  
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